## PSJ3 Exhibit 177

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From: Rosen, Burt

Tue 7/7/2009 2:31:05 PM Sent: Subject: RE: Planning meeting

yes

Burt Rosen VP Federal Government Affairs 700 13th St. NW Suite 525 Washington, DC 20005 Office: 202-508-0750

Cell:

**From:** Myra Christopher [mailto:MChristopher@practicalbioethics.org]

**Sent:** Tuesday, July 07, 2009 2:30 PM

To: Will Rowe; Al Anderson; aducca@hdmanet.org; Buckalew, Judi; Cassie Hallberg; Ed Michna; France, Kimberly P; Gray Haupt, Courtney; Gregory Terman; Ilisa Halpern Paul; JoAnna Schooler; Justine Coffey; Lisa Morgan; Matt Jachetta; Meagan Hohl; Meredith Nguyen; Meredith Y. Smith; Michelle Martin; Monaco, Carol; Phil Saigh; Riley, Crystal; Roecklein Bryan; Ronna Hauser; Stewart Leavitt; Aaron Gilson; Adam Chrisney; Adam Michael Clark; Andrew Scholnick; Ashli Douglas; Barry Eliot Cole; Bob Saner; Brad Gary; Brad Maruca; Brian Munroe; Rosen, Burt; Carlos Gomez; Caroline Schellhas; Christina Plourde; Christy Torkildson; Claudia Campbell; Courtney Snowden; David Joranson; David Swankin; David Weissman; David Woodmansee; Elizabeth Ernst; Fritz Bittenbender; Gail Katz; Greg Thomas; Jack Kalavritinos; Janet McUlsky; Jason Grove; Jerry Roschwalb; Jim Broatch; Jim Green; Joel Hochman; John Sebby; Jonathan Keyserling; Joy Buck; June Dahl; Karina Tabor; Kathry Tucker; Keysha Brooks-Coley; Tiller, Kimberley; Kristina Lunner; Larrissa Scruggs; Lennie Duensing; Licy Do Canto; Lisa Robin; Marcia Lee Taylor; Marcie Bough; Mark Rasmussen; Marsha Stanton; Mary Pat Aardrup; Mary Bennett; Michael Splaine; Micke Brown; Mike Heffernan; Mike Matoon; Nicole Kelly; Bennett, Pamela (Gov't Affairs); Patrick Plues; Paul Arnstein; Penny Cowan; Peter Slone; Peter VanPelt; Rebecca Kirch; Robert Twillman; Rosemary Garza; Scott Fishman; Scott Melville; Stephen Porada; Steven LaPierre; Steven Lewis; Susan K. Rogers; Susan Nichol; Tamara Sloan Anderson; Tamara Sloan Anderson; Timothy Byrne; Valerie Volpe; Wade Delk; William Vollmer

Cc: Bonnie Weissfeld

Subject: RE: Planning meeting

Will is this EST?

My

**From:** Will Rowe [mailto:wrowe@painfoundation.org]

Sent: Tuesday, July 07, 2009 10:45 AM

**To:** Al Anderson; aducca@hdmanet.org; Buckalew, Judi; Cassie Hallberg; Ed Michna; France, Kimberly P; Gray Haupt, Courtney; Gregory Terman; Ilisa Halpern Paul; JoAnna Schooler; Justine Coffey; Lisa Morgan; Matt Jachetta; Meagan Hohl; Meredith Nguyen; Meredith Y. Smith; Michelle Martin; Monaco, Carol; Phil Saigh; Riley, Crystal; Roecklein Bryan; Ronna Hauser; Stewart Leavitt; Aaron Gilson; Adam Chrisney; Adam Michael Clark; Andrew Scholnick; Ashli Douglas; Barry Eliot Cole; Bob Saner; Brad Gary; Brad Maruca; Brian Munroe; Burt Rosen; Carlos Gomez; Caroline Schellhas; Christina Plourde; Christy Torkildson; Claudia Campbell; Courtney Snowden; David Joranson; David Swankin; David Weissman; David Woodmansee; Elizabeth Ernst; Fritz Bittenbender; Gail Katz; Greg Thomas; Jack Kalavritinos; Janet McUlsky; Jason Grove; Jerry Roschwalb; Jim Broatch; Jim Green; Joel Hochman;

John Sebby; Jonathan Keyserling; Joy Buck; June Dahl; Karina Tabor; Kathry Tucker; Keysha Brooks-Coley; Kim Tiller; Kristina Lunner; Larrissa Scruggs; Lennie Duensing; Licy Do Canto; Lisa Robin; Marcia Lee Taylor; Marcie Bough; Mark Rasmussen; Marsha Stanton; Mary Pat Aardrup; Mary Bennett; Michael Splaine; Micke Brown; Mike Heffernan; Mike Matoon; Myra Christopher; Nicole Kelly; Pamela Bennett; Patrick Plues; Paul Arnstein; Penny Cowan; Peter Slone; Peter VanPelt; Rebecca Kirch; Robert Twillman; Rosemary Garza; Scott Fishman; Scott Melville; Stephen Porada; Steven LaPierre; Steven Lewis; Susan K. Rogers; Susan Nichol; Tamara Sloan Anderson; Tamara Sloan Anderson; Timothy Byrne; Valerie Volpe; Wade Delk; William Vollmer

**Cc:** Bonnie Weissfeld; Will Rowe **Subject:** Planning meeting

## Dear All:

We have a call scheduled today from 4 to 5 to plan for Dr. Throckmorton's visit with us on Thursday. I've drafted an agenda (see below) for discussion on our call. I want to emphasize that the goal of our meeting is to present and discuss the PCF REMS recommendations. The agenda reflects that goal. I've also included a discussion item on the recent Advisory Committee recommendations. I think that it is important to use the time we have to articulate and explain our recommendations and the ideas behind these recommendations.

It will be tough to keep to the agenda suggested below but I hope that we can be successful in getting through our recommendations and engaging Dr. Throckmorton in a discussion about ways to improve the quality and access to pain care.

## DRAFT Agenda:

- 1. Welcome and introductions (10 minutes) Will and group
- 2. Explanation of the Pain Care Forum and REMS Task Force (Will) 5 minutes
- 3. Dr. Throckmorton—FDA REMS process and comments --- 20 minutes
- 4. PCF Recommendations: (35 minutes)
  - Keeping the process information driven (assign presenter)
  - Size of class: all opioid vs. long acting/transdermal/methadone (assign presenter) (Recommendation about abuse resistant product reviews/approval)
  - Tying educational "certification" process to DEA registration (assign presenter)
  - Educational programming developed by pain education and patient education experts representing principal organizations (assign presenter)
  - Given the size of the effort and the current lack of information about "what works," we should phase-in the REMS program allowing for learning and program improvement before full implementation (assign presenter)
- 5. Perspective of persons living with pain---the big picture including NSAIDS, Vioxx, opioids, REMS, and now acetaminophen, and medical devices for pain relief (Will, 5 minutes)
- 6. Recent panel recommendations, concerns and implications (assign presenter) 15 minutes
- 7. Discussion and defining how to work together to produce best outcomes for people living with pain (All, 30 minutes)

Reminder: The planning call will take place from 4 to 5 ET. The call-in #: 888 477 8316. The participant code is: 803885#.

Will

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